

## **REMARKS**

Favorable reconsideration of the subject patent application is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 5, 9, 10, 17, 18, 19 and 21-25 are under consideration, with claims 5 and 17-19 being in independent format.

The specification has been amended to update the status of related patent applications, to remove language objected to by the Examiner, and to correct a typographical error. Claims 1-4 have been cancelled from the application as being drawn to non-elected inventions. Claim 5 has been amended to clarify that the claimed polypeptides have histatin activity, and claim 9 has been amended to remove reference to claims 18-20. Claim 20 has been cancelled from the application. Newly added claim 21 is drawn to isolated polypeptides comprising at least a functional portion of SEQ ID NO: 10, wherein the polypeptides comprise SEQ ID NO: 14. Support for newly added claim 21 may be found, for example, at page 26, line 27-page 27, line 9, of the specification as originally filed. Newly added claims 22-25 are drawn to subject matter previously recited in claim 9.

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the above amendments constitute new matter. Applicants further submit that the above amendments are not made for reasons of patentability but to focus the claims on subject matter currently of most interest to the assignees of record, and therefore do not give rise to prosecution history estoppel.

### **Claim rejections under 35 USC §112, first paragraph**

Claims 5, 9, 10, 18 and 20 stand rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure. Specifically, the Examiner asserts that the application does not provide enablement for polypeptides encoded by reading frames in SEQ ID NO: 4 other than the reading frame that encodes SEQ ID NO: 10, or for sequences that are 75%, 90% or 95% identical to SEQ ID NO: 10. These rejections are respectfully traversed.

As noted above, claim 20 has been cancelled from the application and claims 9 and 10 have been amended to remove reference to claim 18.

In response to the Restriction Requirement, the claims were limited to the polypeptide sequence of SEQ ID NO: 10, which is encoded by the polynucleotide of SEQ ID NO: 4. The specification clearly teaches that SEQ ID NO: 10 has histatin activity. Amended claim 5 is drawn to polypeptides encoded by the polynucleotide of SEQ ID NO: 4 wherein the polypeptide has histatin activity, with claim 18 being drawn to polypeptides including a sequence having either 75%, 90% or 95% identity to SEQ ID NO: 10, wherein the polypeptide has substantially the same activity as SEQ ID NO: 10. As stated on page 1, line 29-page 2, line 2, of the specification, histatins are known to possess antimicrobial activity, including, for example, the ability to kill the pathogenic yeast, *Candida albicans*. Assays for determining whether polypeptides and/or peptides possess histatin activity (such as the ability to inhibit the growth of *C. albicans in vitro*) are well known in the art and include those taught, for example, in PCT publication WO 96/40768 and by Oppenheim et al. (*J. Biol. Chem.* 261:1177-1182, 1986). Copies of these references are submitted herewith for the Examiner's convenience.

Furthermore, the instant specification clearly identifies a functional domain at residues 31-38 of SEQ ID NO: 10 (provided in SEQ ID NO: 14; see page 26, line 27-page 27, line 9, of the specification). One of skill in the art would thus be guided by the teachings of the specification to make any modifications to the sequence of SEQ ID NO: 10 outside this region.

It is urged that it would be well within the abilities of one of skill in the art, on being provided with the instant specification, to prepare a polypeptide encoded by SEQ ID NO: 4 and/or having at least 75%, 90% or 95% identity to SEQ ID NO: 10, and determine whether that polypeptide has histatin activity using known techniques. It is also submitted that such studies, while being potentially time-consuming and tedious, do not constitute undue experimentation, and further that such studies are routinely carried out by those of skill in the art to which the present invention pertains.

Applicant thus respectfully submits that the pending claims fully satisfy the enablement requirements of 35 USC §112, first paragraph, and that the rejection of claims 5, 9, 10, 18 and 20 under 35 USC §112, first paragraph, may be properly withdrawn.

**Claim rejections under 35 USC §112, second paragraph**

Claims 9, 10, 19 and 20 stand rejected under 35 USC §112, second paragraph, as being vague and indefinite. Specifically, the Examiner has objected to the recitation of polypeptides comprising a functional portion of SEQ ID NO: 10. This rejection is respectfully traversed.

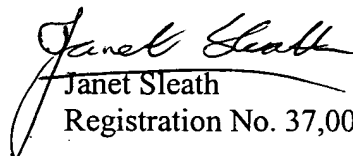
As noted above, claim 20 has been cancelled from the application. In response to the Examiner's objection to claim 19, applicants respectfully draw the Examiner's attention to page 10, lines 1-12, and page 26, line 27- page 27, line 9, where it is clearly stated that the sequences provided in SEQ ID NO: 13 and 14, which are contained within SEQ ID NO: 10, are believed to be a functional domain, or portion, of SEQ ID NO: 10. It is thus urged that the instant specification does indeed "identify with particularity the functional portion of SEQ ID NO: 10."

Applicants thus respectfully submit that one of skill in the art to which the present invention pertains would clearly be able to determine the metes and bounds of the pending claims, and that this rejection of the claims may therefore be properly withdrawn.

Applicants notes that the Examiner has stated that claim 17 is allowable over the prior art of record.

Early reconsideration and allowance of all the pending claims is respectfully requested. Should the Examiner have any further concerns regarding the subject patent application, he is respectfully requested to telephone the undersigned at: 206.382.1191.

Respectfully submitted,

  
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